IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: S. N. Qazi
INDUKUMAR G. SHAH ET AL.	)	
	:	Group Art Unit: 1612
Application No.: 10/671,138	)	
	:	Confirmation No.: 7577
Filed: September 23, 2003	)	
	:	
For: SOLID DOSAGE FORM COMPRISING CAFFEINE	)	August 12, 2011

DECLARATION UNDER 37 CFR 1.132

I, Christopher E. Szymczak, hereby declare:

1. I am one of the joint inventors of U.S. Patent Application Serial No. 10/671,138, entitled "SOLID DOSAGE FORMS CONTAINING CAFFEINE" identified above.

2. I have been employed by McNEIL-PPC, Inc. since May 17, 1999, in the positions of Research Associate, Research Scientist, Senior Research Scientist, Staff Scientist and Principal Scientist. My technical experience includes, but is not limited to, development of dosage form technologies, industrial pharmacy, retail pharmacy, and pharmaceutical materials; and in particular, the formulation, scale-up, validation and commercialization of new pharmaceutical solids formulations.

3. I received a B.S. degree in Pharmacy from the Philadelphia College of Pharmacy (now University of the Sciences in Philadelphia), an M.S. degree in

Pharmaceutics from University of the Sciences in Philadelphia. I am also a licensed pharmacist in good standing registered in the State of New Jersey.

4. I have reviewed the Office Action of May 12, 2011 and have given consideration to the use of caffeine with a granular morphology in the tablet formulation of the present application.

5. I wish to comment on the differences between the terms "granular" and "granulated." These terms have various meanings within the art of industrial pharmacy (e.g. pharmaceutics), which may differ from definitions in other scientific art areas. In pharmaceutics terms, the term "granular" as used in the application refers to a type of particle of a composition, which comprises one kind of material (relatively pure chemical), or one sole type of particle, often a singular crystalline particle of relatively larger particle size compared to a powder form. On the other hand, the term "granulation" refers to an agglomerate formed through compression or wetting of the surface (i.e., wet granulation) containing multiple components in powder form often using one or more chemical binders or other materials, which are capable of binding particles and usually contains a disintegrant to enhance disintegration (thereby increasing the dissolution rate). Thus, the two terms are relate to different concepts.

6. In the present application, the inventive dosage form includes caffeine in the form of uncoated ungranulated particles, which have a granular morphology. That is, the particles are relatively pure chemically and have a larger particle size as compared to caffeine powder. It should be noted that the caffeine particles are not granulated.

7. In addition, I note that in the Office Action, the issue was raised as to the temperature at which the dissolution rate testing was conducted.

8. The specification indicates that the testing was measured by the United States Pharmacopoeia (USP), Type II Apparatus (Paddles) set at 50 rpm. The USP

indicates that dissolution testing for drugs using Type II Apparatus (Paddles) is conducted at a temperature of 37°C.

9. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Christopher E. Szymczak — August 12, 2011

Christopher E. Szymczak — Date: